UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,623	08/16/2006	Lola Weiss	32361	3826

67801 7590 07/06/2010

MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
07/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,623	WEISS ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/06;6/29/07;8/8/08;5/12/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group I, claims 1-18, drawn to a method of treating or preventing of diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a cannabidiol, thereby treating or preventing diabetes is acknowledged. The traversal is on the ground(s) that the claims 1-23 are linked by the general inventive concept of treating diabetes or insulitis with a cannabidiol because the pancreatic cell transplantation is exclusively performed for the treatment of diabetes. This is not found persuasive because each of the condition lacks the same or corresponding special technical features because the patient population having diabetes in Group I do not require having transplanted pancreatic cells. Further, the prolonging the survival of transplanted pancreatic cells is completely different that treatment of diabetes since the treatment of diabetes involves medical disorder while the prolonging survival of pancreatic cells is nurturing event, not necessarily a medical disorder. Therefore, the lack of unity made in the previous Office Action is deemed proper and made final.

The claims 1-18 and newly added claim 24 and 25 are being examined. Claims 19-23 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1, 4-11, 14-18, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 11 are drawn to a method of treating or preventing diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a cannabidiol, whereby treating or preventing diabetes in the subject. The claims thus encompass a broad genus of cannabidiol which must have the property of also being antidiabetic inducing compound.

The premise for the limitation of a cannabidiol appears to be derived from the observation in the instant specification of formula I having single chemical moiety. The specification does not however, indicate why one should assume based on the disclosure of the employment of a single chemical moiety of the broad genus of a cannabidiol is represented without identifying the chemical structural moiety related to the compounds. Given this lack of description of a sufficient number of the

representative species encompasses by the genus of the claim, the specification fails to describe the claimed invention in such full, clear, concise, and exact terms regarding the chemical structure-function relationship that a skilled artisan would not recognize that Applicants were in possession of the claimed invention, "a cannabidiol".

Scope Enablement

1. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treating diabetes", does not reasonably provide enablement for the "**preventing** of diabetes". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

2. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or **preventing** diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a cannabidiol,

thereby treating or **preventing** diabetes in the subject such that the subject treated with above compounds does not contract diabetes.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention of an autoimmune disorder in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to actually prevent diabetes is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention of diabetes.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of diabetes.

State of the Art: While the state of the art is relatively high with regard to treatment of autoimmune disorder (i.e. Lupus, diabetes), the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to prevent development of diabetes.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of diabetes in a human subject

with the claimed compounds makes practicing the claimed invention unpredictable in terms of prevention of diabetes.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for prevention of diabetes. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of diabetes with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of diabetes with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of diabetes in a subject by administration of one of the claimed compounds.

Therefore, a method of treating or **preventing** diabetes in a subject, the method comprising administering to the subject a therapeutically effective amount of a

cannabidiol, thereby treating or **preventing** diabetes in the subject is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by R&D Profile of record (2003).

R&D Profile teaches that cannabis-based product including D9 tetrahydrocannbinol (THC) and cannbidiol (CBD) have been employed as a phase II study in patients with peripheral neuropathy secondary to diabetes mellitus. The phase II trials provided positive results and confirmed an excellent safety profile for cannabis-based medicine.

Applicant's limitation of prevention of diabetes is an inherent effect since it is unavoidable and the claimed "therapeutic amounts" are contemplated by the positive results in the phase II trails provided by R&D Profile.

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hampson et al. (WO 99/53917 A1) of record.

Hampson et al. teaches that cannabinoids have been found to have antioxidant properties that is useful in the treatment of treatment and prophylaxis of autoimmune disease such as diabetes. Hampson et al. teaches that the cannabinoids can be adminsitered via oral, intracranial ventricular, intrathecal, intravenous, parenteral, rectal, topical ophthalmic, subconjunctival, nasal, aural, sub-lingual and transdermal. Hampson teaches therapeutically effective doses of cannabinoids (abstract, page 3, lines 26-30, page 10, lines 31-34; page 11, line 12-27, page 12 ,lines 1-8, page 23, lines 17-19).

Applicant's limitation of prevention of diabetes is an inherent effect and unavoidable upon the administration of the same compound with the same "therapeutically effective" amounts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 11 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampson et al. (WO 99/53917 A1) of record in view of Hill (WO 02/13814A1).

The teachings of Hampson et al as applied as before.

Hampson et al do not teach that the specific type of diabetes, i.e. types I and II and insulitis and the sources of cannabidiol and the subject having transplanted pancreatic cells.

Hill teaches that type I diabetes, insulitis and type II diabetes are dysfunctions of islet and that particularly insulitis and type I diabetes are autoimmune disorders.

It would have been obvious at the time the invention was made to employ cannabinoids taught by Hampson et al for the treatment of diabetes particularly diabetic types I & II and insulitis because Hampson et al. teach that cannabinoids are useful for the treatment of autoimmune disorders including diabetes and inflammatory disorders and because Hill teaches that type I diabetes and insulitis are autoimmune disorder and diabetes II is similarly treated with conditions of type I and insulitis. There is a reasonable expectation of successfully treating diabetes with cannabinoids because cannabinoids are effective for the treatment of inflammatory conditions as well as autoimmune disorders that includes diabetes types I and insulitis. With regard to the source of cannabidiols set forth in claims 4, 5, 14 and 15 are noted. However, such is obvious choice because the effectiveness of cannabidiol of Hampson et al. as having antidiabetic property would be retained regardless of its source. It is noted that the compound and all of its properties are inseparable; they are one and the same thing. With regard to the subjects having transplanted pancreatic cells set forth in claims 24 and 25 are noted. However, such is obvious because again the effectiveness of cannabidiol of Hampson et al. as having antidiabetic effect would be retained regardless of other conditions of the diabetic patients being treated. One of ordinary skill in the art

would be motivated to employ cannbidiol in a patient suffering from diabetes in order to achieve an expected benefit of cannabidiol in the treatment of diabetes regardless of their physical conditions of having transplanted pancreatic cells.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
June 8, 2010